



(B)

150

1649

Dkt. 41426-D/JPW/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ron S. Israeli et al.

Serial No.: 08/470,735

Group Art Unit: 1649

Filed: June 6, 1995

Examiner: S. Gucker

For: PROSTATE-SPECIFIC MEMBRANE ANTIGEN

Date of Notice

Of Allowance: April 20, 2004

Confirmation No.: 7764

1185 Avenue of the Americas
New York, New York 10036
June 7, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the documents identified below, item nos. 3-7 of which are also listed on the attached Form PTO-1449 (**EXHIBIT A**). Copies of the documents identified below as items 1-12 are attached hereto as **EXHIBITS 1 to 12**, respectively. Applicants request that, in accordance with 37 C.F.R. §1.98(i), this Supplemental Information Disclosure Statement be placed in the file of U.S. Serial No. 08/470,735.

1. Notification of Provision of Information mailed March 7, 2006 by Japanese Patent Office to applicants' Japanese representatives in connection with Japanese Patent Application No. 1994-511426 informing these Japanese representatives that a third party had

Applicants: Ron S. Israeli et al.
U.S. Serial No.: 08/470,735
Filed: June 6, 1995
Page 2 of 4

- submitted a "Prior Art Document List" and an English language translation of the Notification; (Exhibit 1)
2. Prior Art Document List submitted by a third party in connection with Japanese Patent Application No. 1994-511426 and an English language translation thereof; (Exhibit 2)
 3. Chandler et al., (1986) Pteroylpolyglutamate Hydrolase from Human Jejunal Brush Borders, J. Biol. Chem., 261(2)928-933; (Exhibit 3)
 4. Silver, D.A. et al., Prostate-Specific Membrane Antigen Expression in Normal and Malignant Human Tissues, Clin. Cancer Res. (1997) 3:81-85; (Exhibit 4)
 5. Chang, S.S. et al., Five Different Anti-Prostate-Specific membrane Antigen (PSMA) Antibodies Confirm PSMA Expression in Tumor-Associated Neovasculature, Cancer Res. (1999) 59:3192-3198; (Exhibit 5)
 6. Lerner, R.A., Antibodies of Predetermined Specificity in Biology and Medicine, (1984) Advances in Immunology 36:1-44; (Exhibit 6)
 7. Brinkmann, U. et al., A Recombinant Immunotoxin Containing a Disulfide-Stabilized Fv Fragment, PNAS, 60(16):7538-7542 (1993); (Exhibit 7)
 8. U.S Patent No. 4,939,240 issued on July 3, 1990 to Chu et al.; (Exhibit 8)
 9. Holmes, Eric H., "PSMA Specific Antibodies And Their Diagnostic And Therapeutic Use," *Exp. Opin. On Invest. Drugs*, 10(3):511-519 (2001); (Exhibit 9)

Applicants: Ron S. Israeli et al.
U.S. Serial No.: 08/470,735
Filed: June 6, 1995
Page 3 of 4

10. Communication Pursuant To Article 115(2) EPC issued August 30, 2004 in connection with related European Patent Application No. 94 90 0538.3; (Exhibit 10)
11. Communication Pursuant To Article 96(2) EPC issued February 8, 2005 in connection with related European Patent Application No. 94 90 0538.3 (Exhibit 11); and
12. Communication Pursuant To Article 115(2) EPC issued March 17, 2005 in connection with related European Patent Application No. 94 90 0538.3 (Exhibit 12).

Applicants note that item no. 3 above was first cited in the Prior Art Document List (item no. 2 above). The existence of the Prior Art Document List was first communicated to applicants in the March 7, 2006 Notification of Provision of Information (item no. 1 above) issued by the Japanese Patent Office in connection with Japanese Patent Application No. 1994-511426. Applicants further note that a second reference listed in the Prior Art Document List, namely Halstead et al. (1998), was previously disclosed in an Information Disclosure Statement filed June 16, 2004 in connection with the above-identified application.

Information Disclosure Statement filed July 11, 1997

Applicants note that there are inadvertent errors in the description of certain documents listed on the PTO-1449 form submitted as part of an Information Disclosure Statement filed July 11, 1997 in connection with the above-identified application. Applicants further note that these documents have already been initialed as considered by the Examiner (see returned PTO-1449 form attached hereto as **Exhibit B**).

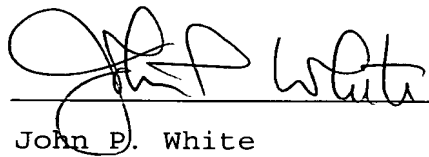
Applicants: Ron S. Israeli et al.
U.S. Serial No.: 08/470,735
Filed: June 6, 1995
Page 4 of 4

Accordingly, applicants request that the Examiner initial the corrected PTO-1449 form attached hereto as **Exhibit C** and return a copy of the initialed, corrected PTO-1449 form to applicants. A copy of the original PTO-1449 form marked to show the changes made is attached hereto as **Exhibit D**.

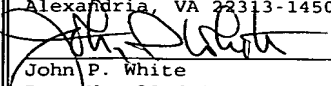
If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

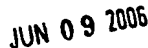
No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
 John P. White Reg. No. 28,678	6/7/06 Date



Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

Complete if Known

Application Number	08/470,735
Filing Date	June 6, 1995
First Named Inventor	Ron S. Israeli
Art Unit	1649
Examiner Name	S. Gucker
Attorney Docket Number	1769/41426-D

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	08/470,735
Filing Date	June 6, 1995
First Named Inventor	Ron S. Israeli
Art Unit	1649
Examiner Name	S. Gucker
Attorney Docket Number	1769/41426-D

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Chandler et al., (1986) Pteroylpolyglutamate Hydrolase from Human Jejunal Brush Borders, J. Biol. Chem., 261(2)928-933	
		Silver, D.A. et al., Prostate-Specific Membrane Antigen Expression in Normal and Malignant Human Tissues, Clin. Cancer Res. (1997) 3:81-85	
		Chang, S.S. et al., Five Different Anti-Prostate-Specific membrane Antigen (PSMA) Antibodies Confirm PSMA Expression, Cancer Res. (1999) Cancer Res. (1999) 59:3192-3198	
		Lerner, R.A., Antibodies of Predetermined Specificity in Biology and Medicine, (1984) Advances in Immunology 36:1-44	
		Brinkmann, U. et al., A Recombinant Immunotoxin Containing a Disulfide-Stabilized Fv Fragment, PNAS, 60(16):7538-7542 (1993)	
		Holmes, Eric H., "PSMA Specific Antibodies And Their Diagnostic And Therapeutic Use," Exp. Opin. On Invest. Drugs, 10(3):511-519 (2001)	
		Communication Pursuant To Article 115(2) EPC issued August 30, 2004 in connection with related European Patent Application No. 94 90 0538.3	
		Communication Pursuant To Article 96(2) EPC issued February 8, 2005 in connection with related European Patent Application No. 94 90 0538.3	
		Communication Pursuant To Article 115(2) EPC issued March 17, 2005 in connection with related European Patent Application No. 94 90 0538.3	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

64477

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

JUN 09 2006

APPLICANT
Ron S. Israeli, et al.FILING DATE:
June 6, 1995GROUP
1806-164

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
56	4 5 5 4 1 0 1	11-19-85	Hopp, T.P. (Exhibit 1)			
11	5 1 6 2 5 0 4	11-10-92	Horoszewicz, J.S. (Exhibit 2)			
11	5 5 3 8 8 6 6	7-23-96	Israeli, R.S., et al. (Exhibit 3)			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translat:
						Yes No
56	WO 9 4 0 9 8 2 0	5-11-94	PCT (Exhibit 4)			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

56	A	Abdel-Nabi, H., et al. (1992) "Monoclonal Antibodies and Radioimmunoconjugates in the Diagnosis and Treatment of Prostate Cancer", Seminars on Urology 127: 45-54 (Exhibit 5);
11	B	Axelrod, H. R., et al. (1968) "Preclinical Results and Humman Immunohistochemical Studies With 90Y-CYT-356: A New Prostate Cancer Therapeutic Agent" AUA 87th Annual Meeting, May 10-14, 1992 (Exhibit 6);
11	C	Carter, B.H. And Coffey, D.S. (1990) "The Prostate: An Increasing Medical Problem" The Prostate 16:39-48 (Exhibit 7);
11	D	Feng, Q., et al. (1991) "Purification and Biochemical Characterization of t 7E11-C5 Prostate Carcinoma-Associated Antigen", Proceedings of the American Association for Cancer Research 32:239 (Exhibit 8);
11	E	Chang, Chawnshang, et al. (1988) "Structural Analysis of Complementary DNA at Amino Acid Sequences of Human and Rat Androgen Receptors", Proc. Natl Acad. Sci USA 85:7211-7215 (Exhibit 9);
11	G	Culver, K.W., et al. (1992) "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors", Science 256:115 1552 (Exhibit 10);
11	H	Decensi, A., et al. (1991) "Phase II Study of the Pure Non-steroidal Antiandrogen Nilutamide in Prostatic Cancer", Eur J Cancer 27:1100-1104 (Exhibit 11);
11	I	Faber, P.W., et al. (1991) "Characterization of the Human Androgen Transcription Unit" The Journal of Biological Chemistry 266:10743-10749 (Exhibit 12);
11	J	Fey, Martin F., et al. (1991) "The Polymerase Chain Reaction: A New Tool for the Detection of Minimal Residual Disease in Haematological Malignancies" E J Cancer 27:89-94 (Exhibit 13);
11	K	Henttu, Pirkko and Vihko, Pirkko (1989) "cDNA Coding for the Entire Human Prostate Specific Antigen Shows High Homologies to the Human Tissue Kallikrein Genes" Biochemical and Biophysical Research Communications 160:903-910 (Exhibit 14);

EXAMINER Stephen Isacke DATE CONSIDERED 10/21/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance

Applicants: Ron S. Israeli et al.
Serial No.: 08/470,735
Filed: June 6, 1995
Exhibit B

64477

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

JUN 09 2006

APPLICANT
Ron S. Israeli, et al.FILING DATE:
June 6, 1995GROUP
1806 164

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Form	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

56	A	Horoszewicz, Julius S., et al. (1987) "Monoclonal Antibodies to a New Anti Marker in Epithelial Prostatic Cells and Serum of Prostatic Cancer Patient AntiCancer Research 7:927-936 (Exhibit 15);
((B	Huber, Brian E., et al (1991) "Retroviral-mediated Gene Therapy for the Treatment of Hepatocellular Carcinoma: An Innovative Approach for Cancer Therapy" Proc. Natl. Acad. Sci. USA 88:8039-8043 (Exhibit 16);
((C	Israeli, Ron S., et al. (1994) "Expression of the Prostate Specific Membrane Antigen" Cancer Research 54:1807-1811 (Exhibit 17);
((D	Israeli, Ron S., et al. (1994) "Sensitive Nested Reverse Transcription Polymerase Chain Reaction Detection of Circulating Prostatic Tumor Cells: Comparison of Prostate-specific Membrane Antigen and Prostate-specific Antigen-based Assays" Cancer Research 5:6306-6310 (Exhibit 18);
((E	Keer, Harold N., et al. (1990) "Elevated Transferrin Receptor Content in Human Prostate Cancer Cell Lines Assessed In Vitro and In Vivo" The Journal of Urology 143:381-385 (Exhibit 19);
((F	Lopes, A. Dwight., et al (1993) "Immunohistochemical and Pharmacokinetic Characterization of the Site-specific Immunocjugate CYT-356 Derived from Antiprostate Monoclonal Antibody" Cancer Research 50: 6423-6429 (Exhibit 2
((G	Lubahn, Dennis B., et al. (1989) "Sequence of the Intron/exon junctions of the Coding Region of the Human Androgen Receptor Gene and Identification of Point Mutation in a family with Complete Androgen Insensitivity" Proc. Nat Acad. Sci. USA 86:9534-9538 (Exhibit 21);
((H	Lundwall, Ake and Lilja, Hans., (1987) "Molecular Cloning of Human Prostate Specific Antigen cDNA" FEBS Letters 214, No. 2:317-322 (Exhibit 22);
((I	Mukhopadhyay, Tapas., et al. (1991) "Specific Inhibition of K-ras Expression and Tumorigenicity of Lung Cancer Cells by Antisense RNA" Cancer Research 51:1744-1748 (Exhibit 23);
((J	Riegman, P.H.J., et al. (1989) "The Prostate-Specific Antigen Gene and the Human Glandular Kallikrein-1 Gene are Tandemly Located on Chromosome 19" F Letters Vol 247:123-126 (Exhibit 24);
((K	Sharief, Farida S., et al. "Human Prostatic Acid Phosphatase: cDNA Cloning Gene Mapping and Protein Sequence Homology With Lysosomal Acid Phosphatase" Biochemical and Biophysical Research Communications 160:79-86 (Exhibit 25)
((L	Solin, Timo., (1990) "Gene Expression and Prostate Specificity of Human Prostatic Acid Phosphatase (PAP): Evaluation By RNA Blot Analyses" Biochem et Biophysica Acta 1048:72-77 (Exhibit 26);

EXAMINER

Stephen Guckey

DATE CONSIDERED

10/21/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include

64477

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

JUN 09 2006

APPLICANT

Ron S. Israeli, et al.

FILING DATE:
June 6, 1995GROUP
1806

1647

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

56	A	Troyer, John K., et al. (1994) "Biochemical Characterization and Mapping of the 7E11-C5.3 Epitope of the Prostate Specific Membrane Antigen (PSMA)" Basic and Clinical Aspects of Prostate Cancer: Abstract C38 (Exhibit 27);
11	B	Su, S.L., et al. (1994) "Sensitive Detection of Prostatic Hematogenous Micrometastases Using Prostate Specific Antigen (PSA) and Prostate Specific Membrane Antigen (PSM) Derived primers in the Polymerase Chain Reaction" Proceedings of the American Association for Cancer Research 35:271 (Exhibit 28);
11	C	Vihko, Pirkko, et al (1988) "Molecular Cloning and Sequence Analysis of cDNA Encoding Human Prostatic Acid Phosphatase" FEBS Letters 236:275-281 (Exhibit 29);
11	D	Vile, Richard G. And Ian R. Hart., (1993) "In Vitro and In Vivo Targeting of Gene Expression to Melanoma Cells" Cancer Research 53:962-967 (Exhibit 30);
11	E	Israeli, Ron S., et al. (1994) "Expression of the Prostate Specific Membrane Antigen" Cancer Research 54:1807-1811 (Exhibit 31);
11	F	Waibel, R., et al. (1990) "Therapy of Small Cell Lung Cancer Xenografts in Nude Mouse model: Evaluation of Radioimmunotherapy and Immunotoxin Therapy" Antibody Immunoconjugates and Radiopharmaceuticals 3:54 (Exhibit 32);
11	G	Watt, Kenneth W.K., et al (1986) "Human Prostate-Specific Antigen: Structure and Functional Similarity With Serine Proteases" Proc. Natl. Acad. Sci. USA 83:3166-3170 (Exhibit 33);
11	H	Wright, Jr., et al "Characterization of a New Prostate Carcinoma-Associated Marker" Antibody Immunoconjugates and Radiopharmaceuticals 3:89 (Exhibit 34); NO DATE
11	I	Young, Richard A. and Davis, Ronald W., "Efficient Isolation of Genes by Using Antibody Probes" Proc. Natl. Acad. Sci. USA 80:1194-1198 (Exhibit 35)
11	J	Israeli, R.S. et al., (1994) "Sensitive Detection of Prostatic Hematogenous Micro-Metastases Using Prostate Specific Antigen (PSA) And Prostate specific Membrane Antigen (PSM) Derived Primers in the Polymerase Chain Reaction (PCR)" J Urol 151:373A (Exhibit 36);
11	K	Israeli, R.S. et al., (1994) "Localization of the Prostate Specific Membrane Antigen (PSM) to the Putative Metastasis-Suppressor Region on Human Chromosome 11" J Urol 151:252A (Exhibit 37);

EXAMINER

Stephen Zucker

DATE CONSIDERED

10/21/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.

Form PTO-1449 (Substituted)
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

ATTY DOCKET NO.
41426-D/JPW/MS

APPLICATION
08/470,735

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

APPLICANT

Ron S. Israeli, et al.

FILING DATE:
June 6, 1995

GROUP

1806 164

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
					Yes No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

56	A	Corr, J.G. et al., (1994) "Prostate Specific Membrane Antigen (PSM) Expression in Orthotopically Implanted Human Prostate Cancer Cells in Nude Mice Slows Tumor Growth and Metastatic Potential" J Urol 151:492A (Exhibit 38);
11	B	Israeli, R.S. et al., (1994) "Localization of the Prostate Specific Membrane Antigen (PSM) to the Putative Metastasis-Suppressor Region on Human Chromosome 11" Proceedings of the American Association for Cancer Research 35:271 (Exhibit 39);
11	C	Israeli, R.S. et al., (1993) "Characterization of the Prostate-Specific Membrane Antigen (PSM)" Cancer Research 34:255 (Exhibit 40);
11	D	Israeli, R.S. et al., (1993) "Molecular Cloning and Characterization of a Prostate-Specific Membrane Antigen" J Urol 149:471A (Exhibit 41);
	E	Israeli, R.S. et al., (1992) "Purification and Molecular Cloning of a New Prostate-Specific Antigen" Cancer Research 33:356 (Exhibit 42).

EXAMINER

Stephen Lucker

DATE CONSIDERED

10/31/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.